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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,063	08/30/2003	Douglas J. Dellinger	10031260-1	9780

7590 06/04/2007

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/652,063	DELLINGER ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 5, 2007 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

The Abstract is objected to as too brief and lacking an adequate description of the claimed invention. Examiner suggests an amended Abstract should include at least one chemical structure disclosing the compounds being claimed.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

The above objection to the Abstract has been updated and maintained as indicated in the second full paragraph above.

Claim **9** has been cancelled, claims **1, 4-6, 10-12 and 14** have been amended, the disclosure has been amended at page 1 and in the Abstract, and no new claims have been added as per the response filed March 5, 2007. No additional Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1-8 and 10-23** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-8 and 10-23** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for a phosphoramidite-based solid-support modification, does not reasonably provide enablement for any other mode of oligonucleotide solid-support synthesis wherein the coupling reaction relies on a different chemistry; e.g. H-phosphonate, phosphate triester, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The instant claims are directed to reagents which may be contacted with a solid support to prepare same for oligonucleotide synthesis and the process of said solid support derivatization, a process wherein the "reagents" are only schematically represented and functionally defined. This description includes a vast array of chemical species because, except for the trityl-type linker group as a portion of the solid support linker moiety, the structural components and their points of linkage are only described with functional language.

B. The nature of the invention: the invention is directed to processes applying compounds usable in the synthesis of oligonucleotide synthesis-capable solid supports and to said compounds referred to herein as "reagent." .

C. The state of the prior art: inspection of the prior art, as determined by the instant PTO-1449 and PTO-892 references, indicates that there are presently no references which read on the entirety of the instant claimed subject matter, particularly the process being disclosed, aside from applicant's own work. However, because the process being claimed is very indefinitely defined, it is presently unclear whether other prior art may be relevant.

D. The level of one or ordinary skill: the general level of one of ordinary skill in the art is high in view of the extensive history of oligonucleotide support syntheses and reagents therefore already developed. However, the minimal disclosure of guidance concerning the application of the instant disclosed process wherein a very small number of oligonucleotide

solid-support derivatizing reagents have been prepared suggests that the skill level of the ordinary practitioner in using the instant claimed compounds must be very low in areas not specifically supported by applicant's exemplifications.

E. The level of predictability in the art: predictability is inversely related to the number of examples supporting the entire breadth of the claims. In light of the very low number of examples predictability is presently very low, particularly for linking chemisties other than the phosphoramidite type.

F. The amount of direction provided by the inventor: the instant disclosure has only a few relevant experimental examples directed to specific exemplifications and, the descriptions of how to make are very brief and are not accompanied by very much data to demonstrate characterization of all of the many possible embodiments claimed by not enabled.

G. The existence of working examples: working examples are few in number, as noted above.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In light of the reliance of the instant generic claim **1** and claim **13** on very broad and functional terminology, and the complete absence of an the appearance of the any specific "reactive group" in either claim, the instant generic claims are deemed to be in the main excessively broad and not well supported by the instant oligonucleotide solid support preparative examples which are limited to the application of phosphoramidite-type linking chemistry to and silica type supports. Therefore, the quantity of experimentation needed to make or use the invention is deemed to be excessive and undue because of the failure of the instant disclosure to provide sufficient examples incorporating coupling chemistries other than the phosphoramidite type to adequately support the scope of claimed subject matter as presently in the case.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicant's amendments to the claims are noted but are found to be incompletely responsive to the above rejection. Examiner notes applicant's amendments to claim **1** and has addressed these changes in subsequent rejections as well as in this response. Examiner notes

the newly added functional terms in claim **1** wherein the scope of the instant claimed subject matter has been narrowed, but the scope remains excessively broad. The instant claimed compounds are not defined in sufficient detail to permit the ordinary practitioner to understand the particular structures being claimed because the essential chemical structural details provided are simply not present. For example the generic structures provides fail to provide a complete structural representation of each and every structural element of the component parts of the claimed compounds and how these component parts are actually attached to form any complete molecular species encompassed by the instant claims. Examiner also notes that claim **7** includes a large number of obviously inoperative embodiments (amino (4 occurrences), hydroxyl (2 occurrences), phospho, nitro, nitroso and carboxy) wherein the noted embodiments will react internally (coupling or redox) or in a polymerization reaction with instant phosphoramidite group (claim **1**, structure VI). Examiner also notes that reliance on the term "substituted" and the absence of subsequent definitions of what particular substituents are implied thereby in the body of the relevant claims.

Claims **4 and 5** are objected to because of the following informalities:

In claim **4** at line 3, term "thiophenyl" is incomplete. Did applicant intend the term to read -- thiophen-2-yl-- or --thiphen-3-yl --? See also claim **5** for the same problem. These changes will avoid confusion concerning the particular structures of the substituents specified. Alternatively, the terms -- 2-thienyl -- and/or -- 3-thienyl -- may be employed.

Appropriate correction is required.

Claims **1-8 and 10-23** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **1-8 and 10-12** the "reagents" being claimed are not described in sufficient detail to permit the ordinary practitioner to know what particular chemical intermediates is/are being claimed. For example, in claim **1** there is no complete chemical structure(s) provided to illustrate the particular reagent(s being claimed; the genus is only hinted at as if applicant is hiding the ball. And, in spite of the particular provisos in claims **2 and 3**, claims **4, 5 and 6** lack proper antecedent basis because the limitation of the noted provisos is violated in each of the second set of claims (no "reactive phosphorus group" attachment is permitted or provided

for in any one of claims **4-6**). See also claim **22** wherein the term "optionally substituted aryl group" implies a similar violation of a previous claim proviso.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Functional language is insufficient to completely describe the details of either reagents or chemical process steps. Applicant is respectfully requested to provide a complete description of the claimed subject matter in the claims.

In claims **13-23** the process being claimed is not described in sufficient detail to permit the ordinary practitioner to know what chemical process step/steps is/are being claimed. For example, in claim **13** there is no chemical process step specifically described; the process is only hinted at as if applicant is hiding the ball. Examiner suggests that claim **13** should be amended to include all of the details necessary to define a chemical process including each and every essential chemical reagent or reactant in a non-functional manner. This is necessary because presently the instant claim is not a proper process claim for failure to define a chemical process step.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Functional language is insufficient to completely describe the details of chemical process steps. Applicant is respectfully requested to provide a complete description of the claimed subject matter in the claims.

In claim **1** at lines 1-18 the structures of the precursor compounds are not completely described because the particular linkages between the component parts of "structure (I)" have not been entirely specified. Functional terminology is not an effective substitute for a complete chemical formula. The same problem reoccurs in claim **13** wherein the "functionalized support" and its component parts have not been described in sufficient detail to permit the ordinary practitioner to determine the structure of the materials being referred to or the locations of the "substituents" the structures of which have been specified functionally or not at all.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicant's response is noted. Applicant is again respectfully requested to amend the claims to completely define the subject matter being claimed.

In claim **2** at line 8, the term "substituted aryl" is incomplete because the substituents implied thereby have not been defined. See also claims **3-4, 10, 11, 12, 14, 15, 16 and 21** wherein the same or very similar errors occur.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicantis respectfully requested to completely define the claimed subject matter in the claims.

In claim **7** at lines 7 and 9-11, a number of substituents lists are obvious non-operative embodiments, including "hydroxyl," "amino," "nitro," "nitroso" and "carboxy," each of which will react competitively to generate side coupling products or redox products.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Unless applicant is trying to make polymers of a kind different that oligonucleotides with 3'->5' linkages, applicant is respectfully requested to delete each and every one of these obviously inoperative emnbodiments.

Claims **18 and 19** appear to be directed to subject matter not relevant to the subject matters of claims **1 and 13** and thereby lacks proper antecedent basis.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicant is claiming a process step. Examiner has one question: what is the structure of the product?

In claim **20** at lines 4-5, the term "the bond via which the reactive nucleoside group is attached to the nucleoside moiety" refers to subject matter not provided for in either claim **13** or claim **1**, thereby rendering the instant claim lacking in proper antecedent basis.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive.

Applicant's response is noted. Examiner's view is that applicant has so relied on functional terminology that the claims simply fail to descibe the invention in sufficient detail to permit determination with any degree of certainty what chemical species applicant is claiming or what porcess these chemical specieis are part of to achieve the results of the claimed process.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-**

0651. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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05/29/2007

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